

## REMARKS

### Rejection of Claims 51-54 and 57 Under 35 U.S.C. § 101

The Office maintained its rejection of claims 51-54 and 57 under 35 U.S.C. § 101, alleging that "the claimed invention is not supported by a substantial asserted utility or a well-established utility." (Office Action at 2.) Claims 51-54 and 57 stand rejected for lack of utility entirely on the basis that the specification does not demonstrate that the peptides have GDP-D-mannose dehydratase activity, based on their homology (51%) with known GDP-D-mannose dehydratases. Applicant respectfully traverses.

The claimed peptides have a substantial, and well-established, utility of distinguishing *M. tuberculosis* from *M. bovis*. The claims recite a purified polypeptide encoded by a polynucleotide comprising an open reading frame ("ORF") contained within SEQ ID NO:1. SEQ ID NO:1 corresponds to a region of about 12.7 kb, which contains ORF6 (specification at ¶¶86 and ¶¶92), and is present in the genome of *M. tuberculosis*, but not *M. bovis*. (Specification at ¶¶66 and ¶¶257.) This region encodes one or more polypeptides. (Specification at ¶¶63.) The polypeptides encoded by this region would be different than polypeptides encoded by the *M. bovis* genome and can be used to distinguish the two strains.

The utility of distinguishing between the two *Mycobacterium* strains is a substantial, present, real-world use, for example, by employing the polypeptides in immunoassays. The encoded polypeptides can be used in diagnostic immunoassays to distinguish a subject infected with *M. tuberculosis* from someone vaccinated with *M.*

*bovis*. (Specification at ¶73.) Applicant accordingly respectfully requests that the Office withdraw its rejection of claims 51-54 and 57 under 35 U.S.C. § 101.

**Rejection of Claims 51-54 and 57 Under 35 U.S.C. § 112, 1st Paragraph, Enablement**

Claims 51-54 and 57 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. The Office states that, because the invention is not supported by a substantial utility, "one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation." (Office Action at 5.)

In response, Applicant courteously submits that the claims are supported by a substantial and well-established utility in view of the foregoing arguments, and thus are fully enabled. Applicant relies on the specific provisions of the M.P.E.P. regarding the relationship between 35 U.S.C. § 101 and § 112, which reads as follows:

Office personnel should not impose a 35 U.S.C. § 112, first paragraph rejection grounded on a "lack of utility" basis unless a 35 U.S.C. § 101 rejection is proper.

(M.P.E.P. § 2107.01, IV.) Accordingly, Applicant respectfully submits that the rejection of claims 51-54 and 57, under 35 U.S.C. § 112, first paragraph, can be withdrawn concurrently with the withdrawal of the rejection under 35 U.S.C. § 101.

**Conclusion**

In view of the foregoing remarks, Applicant requests the Office's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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